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March 26, 2015

Dear Health Care Provider,

This letter is to communicate that the CDC and the U.S. Public Health Service have released new clinical guidelines recommending health care providers consider prescribing pre-exposure prophylaxis (PrEP) for patients at significant risk for HIV. The strategy of providing daily oral antiretroviral drugs continuously to uninfected individuals prior to HIV exposure, known as PrEP, has been shown to reduce HIV acquisition among all populations at high risk. The Illinois Department of Public Health supports the provision of PrEP as an evidence based biomedical intervention to prevent HIV infections.

These new guidelines were developed by the CDC in close partnership with health care providers like you, public health professionals, community stakeholders and other federal agencies. The guidelines recommend that providers consider PrEP as a prevention option for patients who meet specified risk criteria. They also underscore the importance of counseling that covers medication adherence and behavioral HIV risk reduction and recommend regular monitoring of HIV status, side effects, toxicities and risk behaviors.

More specifically, the guidelines recommend PrEP for HIV-uninfected patients with any of the following indications:

- Is in an ongoing relationship with an HIV-infected partner.
- Is not in a mutually monogamous relationship with a partner who recently tested HIV-negative, and who is:
 - A gay or bisexual man who has had sex without a condom or been diagnosed with a sexually transmitted infection within the past six months.
 - A heterosexual man or woman who does not regularly use condoms when having sex with partners known to be at risk for HIV (for example, injecting drug users or bisexual male partners of unknown HIV status) or whose partners are from communities with high rates of HIV infection.
- Has injected illicit drugs within the past six months and has shared equipment or been in drug treatment within the past six months.

For sexually-active people, since no single prevention strategy is 100% effective, the guidelines also recommend that physicians encourage patients to use PrEP with other proven prevention strategies including the use of condoms, lubrication or other risk reduction strategies to provide even greater protection than when used alone. PrEP is not a replacement for safer sex practices.

Truvada for PrEP has been approved with a Risk Evaluation and Mitigation Strategy (REMS). The central component of this REMS is a prescriber training and education program to assist prescribers in counseling and managing individuals who are taking or considering Truvada for PrEP. The training and education program does not restrict distribution of Truvada but provides information about essential elements of a comprehensive HIV prevention strategy. The REMS for Truvada can be found here: http://www.truvadapreprems.com

PrEP has the potential to alter the course of the U.S. epidemic, if targeted to populations in need and used as directed. In fact, CDC estimates that as many as 275,000 HIV uninfected gay men and 140,000 HIV serodiscordant heterosexual couples could benefit from this intervention. Ultimately, the role of PrEP in preventing new HIV infections will depend on: its acceptability to users; how effectively it is delivered by health care providers, including support for patients to achieve high medication adherence and prevent increases in risk behavior; and access to the drug by those at substantial risk of HIV.

As a clinician, you play a critical role in helping to realize the promise of PrEP for HIV prevention in the Illinois. Research shows that the doctor-patient relationship is a powerful one – what you say to your patients can have a great impact on their behaviors and health care choices.

Starting today, you can take several key steps to help expand uptake of PrEP and help address some of the practical issues for its effective delivery. These include:

- Prescribing PrEP to those patients with indications for its use
- Increasing awareness of this safe and effective HIV prevention intervention
- Creating an open dialogue with patients to screen for behaviors that may result in HIV acquisition, communicate prevention messages and reinforce safer behaviors
- Communicating to patients in HIV-discordant relationships that PrEP is an available option for the HIV-negative partner

The new guidelines and clinical providers' supplement are published in full at: <a href="https://doi.org/10.2016/nc.20

For more information on efforts around PrEP implementation in the United States, visit PrEP Implementation

For more information on accessing Gilead's Medication Assistance Program, please visit: Gilead's Medication Assistance Program

Your role in ensuring effective delivery of PrEP is crucial. We trust that these guidelines will give you the information and confidence you need to prescribe and support PrEP use for eligible patients for whom this intervention will prove beneficial.

Additionally, if you are a prescribing clinician and would like to be added to our referral database for PrEP, please submit your name, clinic address, clinic hours, phone number and name of your primary office contact person to the Illinois Department of Public Health at:

Angela.Daidone@illinois.gov

Sincerely,

Medical Director

Division of Infectious Disease

Illinois Department of Public Health